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10/655,920	09/05/2003	Hassan Mostafavi	VM7031422001	8620

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EXAMINER	
LAURITZEN, AMANDA L	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/655,920	MOSTAFAVI, HASSAN	
	Examiner	Art Unit	
	A. Lauritzen	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 31-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This action is in response to communications filed 3 July 2008. Amendments to the claims are not interpreted to introduce new matter.

Response to Arguments

Applicant's arguments with respect to claims 1-9, 10-14, 15-23 and 64-66 in view of Kaufman and Takeo have been fully considered but are not persuasive and/or are moot in view of new grounds of rejection. The composite image of Kaufman (here, reference is made to the paragraph numbers of the pre-grant publication US 2003/0016782) is in fact determined "based on first and second images" that are real-time images (see, for example, "selection of slices can be displayed to the user in real time" [0058], "allows the user to view in real-time" [0063],...

The composite image (also referred to in the disclosure as a coronal/sagittal projection image) is in fact a result of selection of at least first and second slice images [0098]. The real-time slice images are selected and the composite projection is generated based thereon, also in real-time as the slices (corresponding to the first and second images) are selected [0093].

Additionally, real-time image acquisition schemes are replete in the medical diagnostic imaging art and if it is construed that the systems and/or combination of systems cited in the rejection are not capable of providing real time gating, it is regarded as an obvious difference. Examiner maintains that the combination of references teaches gating of a medical procedure (radiation therapy or otherwise) based upon an image or composite image (as in Kaufman et al.) with modification by Takeo to meet the subtraction imaging limitations.

Regarding Fitzgerald, the templates of the claims is corresponded to the treatment planning records of the reference. The treatment planning record includes both image and treatment data [0012]. Additionally, [0014] presents that treatment plans include a visual

representation of the radiation dose distribution (an image), with the dose being treatment data. Multiple radiation plans are disclosed at [0023].

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 1-9, 10-14, 15-23, 24-29, 31-33, 34-39, 40-48, 49-54, 55-57, 58-63 and 64-66 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim sets are each regarded generally as process execution steps (including computer-readable processes that correspond to the execution of the claimed method steps), and in order for a process claim to be patentable under 35 U.S.C. 101, per *In re Bilski*, it must be tied to another statutory class (such as a particular apparatus), or transform underlying subject matter (such as an article or materials) to a different state or thing. The claim(s) must positively recite the thing or product to which the process is tied, for example, by identifying the specific apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example, by identifying the material that is being changed to a different state.

In the instant case, the claims do not positively recite use of a particular apparatus to carry out the method steps and are therefore non-statutory. There is not sufficient tie of the claimed subject matte to another statutory class. Additionally, the system claims appear to be directed to execution of a series of process steps and also require tie to a specific statutory class.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-29 and 31-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7-63 of copending Application No. 10/656,478. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to gating a medical procedure based on an image (and/or composite image), with method steps and system components that are identical or obvious variants. It is noted that the instant claims do not specify determining a position of a target region, but based on the conflicting application it is clear that this is accomplished based on the resulting composite subtraction image.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-29 and 31-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-43 and 44-49 of copending Application No. 10/678,741. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to gating a medical procedure based on an image or, in the case of the conflicting claims, based on first and second data signals, which encompasses images.

The above (sections 2 and 3) are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

4. Claims 1-29 and 31-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of US 6,959,266. Although the conflicting claims are not identical, they are not patentably distinct because the conflicting claims are directed to gating radiation therapy based upon first and second sets of data, which encompasses first and second images as in the instant claims.

5. Claims 1-29 and 31-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of US 6,937,696. Although the conflicting claims are not identical, they are not patentably distinct because the conflicting claims are directed to gating radiation therapy based upon first and second sets of data, which encompasses first and second images as in the instant claims. Additionally, the conflicting method is executed in the context of a computed tomography procedure, as in the preamble of claim 1, so it is reasonably assumed that the first and second sets of data as claimed, could correspond to first and second tomographic image datasets.

6. Claims 1-29 and 31-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of US 6,690,965. Although the conflicting claims are not identical, they are not patentably distinct because the conflicting claims are directed to gating a signal chart representing radiation treatment intervals, which reads on the gating of a therapeutic radiation and/or the gating of a medical procedure of the instant claims.

7. Claims 1-29 and 31-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of US 6,621,889. Although the conflicting claims are not identical, they are not patentably distinct because the conflicting claims are directed to gating radiation therapy based upon first and second sets of data, which encompasses first and second images as in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. (US 7,006,862) in view of Takeo (US 6,125,166).

Kaufman discloses a system and associated method in which radiation therapy is gated by an ECG signal, that involves at least first and second real-time images and forming a composite image with thresholding pixel (contrast) values in the activation/deactivation of a therapeutic

radiation (abstract; Fig. 16; col. 5; col. 14; col. 20, lines 16-23; col. 3, lines 32-45; col. 8, lines 8-14; col. 13, lines 24-33; col. 2, lines 57-64; col. 9, lines 10-17; inter alia). Kaufman et al. do not expressly teach conducting a subtraction operation among images, but where Kaufman is deficient, Takeo establishes what is conventional within the skill of the art. Takeo discloses a method of forming energy subtraction images and discloses using contrast values to determine threshold values (col. 1, lines 50-64 for the subtraction process; also col. 19, lines 11-28 in which a contrast value is used). It would have been obvious to use a contrast value of the image for reference as taught by Takeo in the system of Kaufman et al. for determining a threshold value in the gating of a procedure, as contrast image data allows for extraction of a specific image structure that would be receiving treatment (for motivation, see Takeo at col. 2, lines 23-24).

9. Claims 24-29, 32, 33, 34-39, 40-48 and 49-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Takeo, as applied in section 1 above, further in view of Fitzgerald (US 2005/0027196).

Kaufman et al. as appended by Takeo includes all features of the invention as substantially claimed, including enhancing a moving object except for providing templates that include both image and radiation treatment data. In the same field of endeavor, Fitzgerald teach where Kaufman and Takeo are deficient – specifically providing templates, records or what is generally known as a radiation treatment plan that prescribes imaging information and information related to radiation therapy [0012], [0023]. The templates of the claims is corresponded to the treatment planning records of Fitzgerald. The treatment planning record includes both image and treatment data [0012]. Additionally, [0014] presents that treatment plans include a visual representation of the radiation dose distribution (an image), with the dose

being treatment data. Multiple radiation plans are disclosed at [0023]. It would have been obvious to one of ordinary skill in the art at the time of invention to provide templates specific to both the imaging and radiation therapy protocol for the purpose of planning guided treatment, as taught by Fitzgerald.

Regarding claims 49-66, Fitzgerald teaches tracking the position of a target area in that the treatment planning accommodates tracking the location and disposition of a radiation beam with respect to a target anatomical area [0022]. The position of sources is verified with an imaging step [0023]. It would have been obvious to one of ordinary skill in the art at the time of invention to include position tracking in the radiation therapy gating scheme of Kaufman et al. as appended by the image subtraction scheme of Takeo as taught by Fitzgerald.

10. Claims 49-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Takeo, as applied in section 1 above, further in view of Verard et al. (US 2004/0097805).

Kaufman et al. as appended by Takeo includes all features of the invention as substantially claimed, including enhancing a moving object except for providing templates that include both image and treatment data. In the same field of endeavor, Verard et al. disclose registration images with templates (para. 112 and para. 132 in which templates provide treatment data that includes lead placement and para. 146 for templates that provide therapy effective zones). It would have been obvious to one of ordinary skill in the art at the time of invention to have incorporated template registration as taught by Verard et al. with the system of Riaziat et al. in order to optimize the procedure (for motivation, see Verard para. 146). Takeo et al. teach image averaging for the purpose of smoothing an image (col. 13, lines 36-46). It would have

been obvious to incorporate image averaging as taught by Takeo with the modified system of Kaufman et al. in order to smooth images in the sequence. Features in the depending claims are clearly taught in the references applied or are considered to be obvious within the skill of the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Lauritzen whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. L./
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